

REMARKS

Claims 1, 3-20 and 22-38 are currently pending in the application. By this amendment, independent claims 1, 3, 20 and 22 will have been amended to further clarify Applicant's claimed invention. No new matter has been entered.

Accordingly, reconsideration and withdrawal of the pending rejections are requested in view of the instant amendments and the accompanying remarks.

Amendment Fully Supported by the Original Disclosure

The above amendments do not add new matter to the application and are fully supported by the specification. For example, support for amending independent claims 1 and 20 is provided in paragraphs [0004], [0005] and [0032]. Claims 3 and 22 were amended to further clarify that the first component material is an elastic polymeric material and the second component material is a substantially inelastic polymeric material. For example, support for amending claims 3 and 22 is provided in paragraphs [0004], [0005] and [0032].

Drawings

As neither the Examiner nor the Patent Office Draftsperson has objected to the originally submitted drawings, Applicant understands that these drawings are acceptable.

35 U.S.C. §103 Rejection**1. LEBNER in view of LUTRI**

Claims 1, 3-20 and 22-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lebner (US Patent No. 6,329,564) (hereafter "LEBNER") in view of Lutri et al. (U.S. Published Patent Application 2004/0106888) (hereafter "LUTRI"). This rejection is respectfully traversed. Applicant brings forth the following remarks concerning the Examiner's assertions in the office action dated May 15, 2006:

- (1) Applicant submits that no proper combination of LEBNER and LUTRI teach or suggest the features of Applicant's claimed invention, if anything, Applicant submits the Examiner's rejection is based on the use of improper hindsight reconstruction;

(2) Applicant submits the requisite motivation derived by the Examiner must stem from some teaching, suggestion or inference in the prior art as a whole or from knowledge generally available to one of ordinary skill in the art and not from Applicant's disclosure.

The Examiner asserts that LEBNER shows all the features of the claimed invention except for the first and second components being made of an elastic polymeric material, and it would have been obvious to one of ordinary skill in the art to the wound closure bandage as disclosed in LEBNER to have the first and second components made of an elastic material, as taught by LUTRI, to provide greater comfort to the user's skin. Applicant respectfully disagrees with the Examiner's assertions.

Applicant's independent claim 1, as currently amended, recites, *inter alia*:

"A two-component device for closing a laceration or incision, comprising:

- a) a first component comprising a first adhesive-backed anchoring member, the first component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical first component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for a period of time sufficient for the laceration or incision to heal naturally;
- b) one or more first connecting members, produced from a substantially inelastic material, attached to the first adhesive-backed anchoring member and extending from one edge thereof in a first direction;
- c) a second component comprising a second adhesive-backed anchoring member, the second component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical second component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for the period of time sufficient for the laceration or incision to heal naturally;
- d) one or more second connecting members, produced from a substantially inelastic material, attached to the second adhesive-backed anchoring member and extending from one edge thereof in a second direction generally opposite to the first direction;
- e) means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the connecting

members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members."

Applicant's independent claim 20, as currently amended, recites, *inter alia*:

"A method for closing a laceration or incision, the method comprising:

- a) providing a two-component device for closing a laceration or incision, comprising:
 - i) a first component comprising a first adhesive-backed anchoring member, the first component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical first component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for a period of time sufficient for the laceration or incision to heal naturally;
 - ii) one or more first connecting members, produced from a substantially inelastic material, attached to the first adhesive-backed anchoring member and extending from one edge thereof in a first direction;
 - iii) a second component comprising a second adhesive-backed anchoring member, the second component being produced from a material having a degree of elasticity thereby providing improved adhesion relative to an otherwise identical second component produced from an inelastic material while maintaining the physical relationship between wound edges in an applied device for the period of time sufficient for the laceration or incision to heal naturally;
 - iv) one or more second connecting members, produced from a substantially inelastic material, attached to the second adhesive-backed anchoring member and extending from one edge thereof in a second direction generally opposite to the first direction;
 - v) means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members.
- b) attaching the first and second components to the skin on opposite sides of

- the laceration or incision, the edge of the first and second components from which the one or more connecting members extend being the edge closest to the laceration or incision;
- c) closing the laceration or incision by adjusting the position of the first and second anchoring members relative to each other in both an X and a Y dimension; and
 - d) fixing the relationship between the first and second anchoring members established in step c) by attaching the one or more first connecting members to the second anchoring member, and the one or more second connecting members to the second anchoring member.”

Applicant submits the Examiner is using impermissible hindsight reconstruction based on Applicant's disclosure to make an improper combination of LEBNER and LUTRI.

LEBNER shows a bandage for mechanically closing a wound that provides for holding the wound edges in a closed position for a period sufficient for the natural healing process to accrue to the point where removal of the bandage is appropriate. For example, an adhesive used with the bandage would hold for a period for generally about 7-10 days. The bandage 1 of LEBNER includes a plurality of first elongated connectors 15 extending from a wound edge 20 of a first flat flexible component 5 in a first direction, and a plurality of second elongated connectors 35 extending from a wound edge 42 of a second flat flexible component 25 in a second direction, which is generally opposite to the first direction. Further, LEBNER shows the first and second elongated connectors 15 and 35 being produced from a substantially inelastic polymeric material, and the Examiner correctly noted that nothing in LEBNER teaches or suggests a *first and a second component that is elastic*.

LUTRI shows a bandage for simplifying the process for healthcare professionals to follow proper procedure using flowable or liquid adhesives, such as “super glue” adhesive or cyanoacrylates, for bonding wound edges of a wound. The LUTRI patent discloses a bandage that is designed to hold wound edges together just long enough for the super glue adhesive to dry. For example, LUTRI shows a one-piece surgical bandage having two solid tape segments 10, a central, non-absorbent segment of netting 11 and two pull strings 12. See paragraph [0035] of LUTRI. However, Applicant submits that one skilled in the art of wound closure design interested in improving the closure described in the cited

Lebner patent would not look to the Lutri reference for guidance, since the single piece bandage of LUTRI is designed for momentarily holding the wound edges together for a period of time long enough for the “super glue” adhesive to dry.

Applicant submits that, contrary to the Examiner’s assertions, the fact that the claimed invention maybe within the capabilities of one of ordinary skill in the art (which Applicant submits it is not), is not sufficient by itself to establish a *prima facie* obviousness argument. See MPEP 2143.01(IV). Applicant’s wound closure device comprises a first and second adhesive-backed component that cooperates to mechanically close a laceration or incision. The adhesive-backed material is described as polymeric material or film. Further, it is a requirement of Applicant’s device that it maintain closure of the laceration or incision for a period of time sufficient for the natural wound healing process to take place. The device represents a mechanical closure which maintains the edges of the laceration or surgical incision in proximity while the natural healing process takes place.

However, the cited Lutri et al. reference actually teaches away from Applicant’s invention in that Lutri et al. teaches away from the use of an adhesive-backed film for approximating the edges of a laceration or incision while the natural healing process takes place. For example, paragraph 5 of the cited reference states that:

“Tape is simple and fast to use to approximate wound edges and requires little expertise and only minimal experience. However because the strength is dependent on adhesives that are pre-placed on the surface of the tape and are subject to losing their adhesive ability over time or with exposure to moisture, tape may not hold the wound edges close together for a lone enough period of time to allow the natural wound healing process to occur.”

The solution to the wound closure problem presented by Lutri et al. involves the use of a flowable adhesive which is applied to approximate wound edges while the healing process occurs. The tape composite described by Lutri et al. and cited by the Patent Office represents, in essence, a substrate for the application of a flowable adhesive. The adhesive backed portions of the Lutri et al. substrate (for example, items 10 in Fig. 1) need only aid in the approximation of wound edges for a period of less than 3 minutes in order to facilitate the application and setting of one or more layers of a flowable adhesive.

One skilled in the art, interested in improving an adhesive-backed closure system for approximating the edges of a laceration or incision while the natural healing process takes

place would not look for guidance to a reference which provides for wound edge approximation using a flowable adhesive and requires adhesive-backed portions of a tape composite to adhere only long enough for a flowable adhesive to set or harden. To reiterate, Lutri et al. teach in paragraph 0008 that:

“One recent article recommended that the total time that the wound edges should be held closely together is 2 1/2 minutes.”

Thus, one skilled in the art would not look to the Lutri et al. reference for guidance in connection with an adhesive-composite wound closure device intended to approximate the wound edges for a period of time sufficient for the wound to heal naturally (e.g., 7-10 days).

Moreover, as discussed above, one skilled in the art of wound closure design interested in improving the closure described in the cited LEBNER patent would not look to the LUTRI reference for guidance since the LUTRI patent is solving a different problem, e.g., bonding the wound edges for a short period of time, versus the LEBNER patent is solving the problem of bonding the wound edges for a period of time for the nature healing process to occur. Clearly, the Examiner must understand that the applied references are solving two different problems, such that each problem represents different challenges to overcome.

Therefore, Applicant respectfully submits, that the Examiner is using impermissible hindsight based on Applicant's disclosure to make an improper combination of LEBNER and LUTRI.

Furthermore, Applicant notes, the Examiner incorrectly asserts that the reason for combining LUTRI with LEBNER was for the sake of providing comfort to the skin, as discussed above, this is contrary to the teaching of LUTRI. See the end of paragraph [0011] of LUTRI and section 7 of the instant Office Action. Moreover, there is no teaching or suggestion in the Examiner's discussion as disclosed in LUTRI that addresses an objective reason to combine the teachings of the references from one 'well within the ordinary skill of the art at the time the claimed invention was made' (see MPEP 2143.01(IV), that addresses the Applicant's claimed invention, as at least recited in the independent claims. Clearly, the Examiner must be able to understand and appreciate the importance of the Applicant's claimed invention, of creating a solution to a problem of having bandage that has holding capabilities to hold for a period of time sufficient for the

healing process to progress to the point where removal of the device is appropriate.

Thus, for the reasons stated above, Applicant respectfully submits it would not have been obvious to modify the teachings of LEBNER and LUTRI to that of the features of the instant invention.

Moreover, a § 103 rejection requires the Examiner to first establish a *prima facie* case of obviousness: 'To establish a *prima facie* case of obviousness, three basic criteria must be met.' See MPEP 2143.

"**First**, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. **Second**, there must be a reasonable expectation of success. **Finally**, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." See MPEP 2143.

Further, when applying a § 103 rejection 2143.01 (I) of the MPEP states:

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992)." See MPEP 2143.01 (I).

As discussed above, MPEP 2143.01(IV) states a § 103 rejection requires the Examiner to first establish a prima facie case of obviousness: 'The fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish prima facie obviousness'.

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art" at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levingood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.). See MPEP 2143.01(IV).

Further, as discussed above, LUTRI requires bonding the wound edges long enough for the "super glue" adhesive to dry, rather than for providing greater comfort to the user's skin, as asserted by the Examiner. Therefore, Applicant submits that it would not have been obvious to modify LEBNER in such a way to render the instant invention unpatentable, nor is there any suggestion in the art of record that even if obvious (which Applicant submits it is not) LEBNER be modified in the manner asserted by the Examiner would operate in its intended manner.

Applicant submits the rationale for concluding the Examiner's assertions are impermissible hindsight based on Applicant's disclosure, (e.g., it would have been obvious to one of ordinary skill in the art to implement the technique of LUTRI with the device of LEBNER), is in accordance with MPEP 2145 (X), which recites, in part:

Applicants may argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention

was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is "hindsight" because "express" motivation to combine the references is lacking.

Furthermore, as discussed above, Applicant submits that having a bandage that includes the features discussed above, provides significant advantages over the prior art.

Therefore, if not for impermissible hindsight reconstruction, and contrary to the Examiner's assertions, Applicant submits it would not have been obvious to modify LEBNER in such a way to render the instant invention unpatentable, as in accordance with the discussions noted-above.

Further, even assuming, *arguendo*, that LEBNER in view of LUTRI can be combined, which Applicant submits it does not, in accordance with the above-mentioned comments, the Examiner has not shown any rationale (other than discussed above) as to why one ordinarily skilled in the art would be motivated to modify the LEBNER with the two pieces of solid tape of the single-piece bandage of LUTRI, particularly when LUTRI teaches against using tape.

Applicant notes that, under 35 U.S.C. § 103, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have found it obvious to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See *Ex parte Clapp*, 227 USPQ 972 (B.P.A.I. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from Applicant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988). Notwithstanding the Examiner's statement in the rejection that "it would have been obvious to one of ordinary skill in the art to implement the two pieces of solid tape of LUTRI with the device of LEBNER in order to provide greater comfort to the user's skin", to obtain the same advantages," Applicant contends that this is not a reason why one of ordinary skill in the art would have been led to modify any of the devices of the LEBNER device, in view of the features of Applicant's claimed invention as discussed above. Moreover, it is respectfully submitted that the courts have long held that

it is impermissible to use Applicant's claimed invention as an instruction manual or "template" to piece together teachings of the prior art so that the claimed invention is purportedly rendered obvious. See *In re Fritch*, 972 R.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

As the art of record fails to provide the requisite motivation or rationale for combining the LEBNER and LUTRI in the manner asserted by the Examiner, especially in view of the diverging arts and the problems and challenges that each applied references needs to overcome, as discussed above, Applicant submits that the asserted combination is improper and should be withdrawn.

For these reasons, Applicant respectfully submits that independent claims 1 and 20 are allowable over LEBNER and LUTRI or any proper combination thereof, or of any of the prior art of record. Claims 3-20 and 22-38 are also allowable over LEBNER and LUTRI because of their dependency from an allowable base. Withdrawal of the rejection of claims 1, 3-20 and 22-38 is respectfully requested.

2. LEBNER in view of BEAUDRY

Claims 1, 3-20 and 21-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lebner (US Patent No. 6,329,564) (hereafter "LEBNER") in view of Beaudry (U.S. Patent No. 6,982,359) (hereafter "BEAUDRY"). This rejection is respectfully traversed. Applicant brings forth the following:

- (1) Applicant respectfully submits that a *prima facie* case of obviousness has not been established as the applied references of LEBNER and BEAUDRY fail to teach each and every element of the claims.
- (2) Applicant submits that no proper combination of LEBNER and BEAUDRY teach or suggest the features of Applicant's claimed invention, if anything, Applicant submits the Examiner is using impermissible hindsight reconstruction;
- (3) Applicant submits below a review of the § 103 rejection requirements for an Examiner to first establish a *prima facie* case of obviousness according to MPEP 2143, 2143.01(I) and (IV);
- (4) Applicant's submits that the rational for arguing the Examiner's assertions of

impermissible hindsight for the instant Office Action is in accordance with MPEP 2145(X);

- (5) Applicant submits below the requisite motivation derived by the Examiner must stem from some teaching, suggestion or inference in the prior art as a whole or from knowledge generally available to one of ordinary skill in the art and not from Applicant's disclosure.

The Examiner acknowledges that LEBNER lacks, among other things, the first and second components produced from a first polymeric material that is elastic, as at least recited in independent claims 1 and 20. However, the Examiner explains that this feature is taught by BEAUDRY and that it would have been obvious to combine the teachings of these documents. Applicant respectfully submits that a *prima facie* case of obviousness has not been established as the applied references fail to teach each and every element of the claims.

Applicant submits that neither LEBNER nor BEAUDRY disclose or suggest the combination of features recited in at least independent claims 1 and 20. Applicant also submits that no proper combination of these documents disclose or suggest the combination of features recited in at least claims 1 and 20.

As explained above, LEBNER lacks any disclosure or suggestion with regard to the first polymeric material being elastic. With regard to BEAUDRY, Applicant acknowledges that BEAUDRY teaches several wound dressing having an elastic member. See Fig.s 19-25 and 31-93 and Col. 13, line 49 to Col. 19, line 28. However, BEAUDRY lacks any disclosure or suggestion with regard to an anchoring member that is elastic, rather BEAUDRY discloses the elastic member as connected to the anchoring member. See Fig.s 19-25 and 31-66 and Col. 13, line 49 to Col. 18, line 49. Clearly, the Examiner must understand the difference between an elastic member connected to the anchoring member versus the anchoring member being elastic, which is at least recited in Applicant's independent claims 1 and 20.

Further, BEAUDRY discloses a dressing directed to a burnt wound that includes an elastic member connected to the anchoring member, but nowhere in the disclosure is the anchoring member disclosed as being elastic, as at least disclosed in Applicant's claimed

invention. See Fig.s 67-86 and Col. 18, line 50 to Col. 19, line 28. Applicant submits that, there is no teaching or suggestion in the Examiner's discussion that it would have been apparent to those ordinarily skilled in the art to incorporate an elastic anchoring member, as recited in at least the independent claims.

As the BEAUDRY reference fails to provide any teaching or suggestion of such a modification, it is incumbent upon the Examiner to find additional art that teaches, not only the above-noted features which are deficient in BEAUDRY, but also the necessary motivation or rationale for modifying LEBNER to include such features.

Moreover, in addition to failing to disclose the combination of features recited in the above-noted claims 1 and 20, Applicant submit no proper combination of these documents discloses or suggests the combination of features recited in claims 1 and 20 or in the above-noted claims which depend from claims 1 and 20.

Applicant submits that no proper combination of LEBNER and BEAUDRY teach or suggest the above-noted features, if anything, Applicant submits the Examiner is using impermissible hindsight reconstruction.

Applicant submits that, contrary to the Examiner's assertions, as well as discussed above, BEAUDRY teaches an elastic member that is connected to an anchoring member, but not an anchoring member that is disclosed as being elastic.

Furthermore, the combination of references fails to show the subject matter as noted above as deficient in LEBNER alone. As discussed above, the BEAUDRY device does not teach or suggest the anchoring members being elastic, as recited in the independent claims.

Respectfully, Applicant submits that here is no motivation to make such an argument in view of the lack of teaching or suggestion in the applied art that the *first and second component are produced from a first polymeric material*, as at least recited in the independent claims.

Therefore, Applicant respectfully submits it would not have been obvious to modify the teachings of BEAUDRY to that of the features of the instant invention.

Thus, Applicant submits that the art record fails to disclose the requisite motivation or rationale for modifying LEBNER in the manner asserted by the Examiner. If anything, Applicant submits the Examiner is using impermissible hindsight based on Applicant's

disclosure.

Applicant submits that, contrary to the Examiner's assertions, the fact that the claimed invention maybe within the capabilities of one of ordinary skill in the art (which Applicant submits it is not), is not sufficient by itself to establish a *prima facie* obviousness argument. See MPEP 2143.01(IV). Applicant's claimed invention discloses, in part, the *first and second components are produced from a first polymeric material*. LEBNER clearly teaches the first and second flat flexible components are made of inelastic polymeric material. See Col. 2, lines 60-67 of LEBNER. Furthermore, as discussed above, BEAUDRY discloses the elastic members being connected to the anchoring members rather than the anchoring member being elastic.

Moreover, there is no teaching or suggestion in the Examiner's discussion that addresses an objective reason to combine the teachings of the references from one 'well within the ordinary skill of the art at the time the claimed invention was made' (see MPEP 2143.01(IV), that addresses the *first and second components being produced from a first polymeric material*, as at least recited in the independent claims. Clearly, the Examiner must be able to understand and appreciate the importance of the Applicant's claimed invention, of creating a solution to a problem of having elastic first and second components, e.g., having holding capabilities to hold for a period of time sufficient for the healing process to progress to the point where removal of the device is appropriate.

Therefore, for the reasons stated above, Applicant respectfully submits it would not have been obvious to modify the teachings of LEBNER and BEAUDRY to that of the features of the instant invention.

A § 103 rejection requires the Examiner to first establish a *prima facie* case of obviousness: 'To establish a *prima facie* case of obviousness, three basic criteria must be met.' See MPEP 2143. See the referenced statutory on the bottom of page 15 of this paper.

Further, when applying a § 103 rejection according to 2143.01 (I) of the MPEP, the Examiner can only establish obviousness by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the

knowledge generally available to one of ordinary skill in the art. Further, the test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. See the referenced statutory quote on page 15.

Moreover, as discussed above, MPEP 2143.01(IV) states a § 103 rejection requires the Examiner to first establish a *prima facie* case of obviousness: ‘The fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness’. See the referenced statutory quote on page 16 of this paper.

Moreover, there is no teaching or suggestion in BEAUDRY that the anchoring members are elastic, as recited in the independent claims. Therefore, Applicant submits that it would not have been obvious to modify LEBNER in such a way to render the instant invention unpatentable, nor is there any suggestion in the art of record that even if obvious (which Applicant submits it is not) LEBNER be modified in the manner asserted by the Examiner would operate in its intended manner.

Further, Applicant submits the rationale for concluding the Examiner’s assertions are impermissible hindsight reconstruction (e.g., it would have been obvious to one of ordinary skill in the art to implement the technique of BEAUDRY with the device of LEBNER), is in accordance with MPEP 2145 (X). See the referenced statutory quote on the bottom of page 16 and top of page 17 of this paper.

Furthermore, as discussed above, Applicant submits that having elastic first and second component provides significant advantages over the prior art, as at least taught by BEAUDRY. Therefore, if not for impermissible hindsight, and contrary to the Examiner’s assertions, Applicant submits it would not have been obvious to modify LEBNER in such a way to render the instant invention unpatentable, as in accordance with the discussions noted-above.

Further, even assuming, *arguendo*, that LEBNER in view of BEAUDRY can be combined, which Applicant submits it does not in accordance with the above-mentioned comments, the Examiner has not shown any rationale (other than discussed above) as to why one ordinarily skilled in the art would be motivated to modify the LEBNER with the two

why one ordinarily skilled in the art would be motivated to modify the LEBNER with the two pieces of solid tape of the single-piece bandage of BEAUDRY, particularly when the elastic member of BEAUDRY is separate and distinct from the anchoring.

Applicant notes that, under 35 U.S.C. § 103, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have found it obvious to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See *Ex parte Clapp*, 227 USPQ 972 (B.P.A.I. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from Applicant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988). Notwithstanding the Examiner's statement in the rejection that "it would have been obvious to one of ordinary skill in the art to implement the elastic member of BEAUDRY with the device of LEBNER in order to impart different physical characteristics to different parts of the device," Applicant contends that BEAUDRY discloses the elastic member separate and distinct from the anchoring member and that this is not a reason why one of ordinary skill in the art would have been led to modify any of the devices of the LEBNER device, in view of having the *first and second components being produced from a first polymeric material*, which is at least recited in Applicant's claimed invention, as currently amended. Moreover, it is respectfully submitted that the courts have long held that it is impermissible to use Applicant's claimed invention as an instruction manual or "template" to piece together teachings of the prior art so that the claimed invention is purportedly rendered obvious. See *In re Fritch*, 972 R.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

As the art of record fails to provide the requisite motivation or rationale for combining the LEBNER and BEAUDRY in the manner asserted by the Examiner, especially in view of the *first and second components being produced from a first polymeric material*, as at least recited in Applicant's independent claims. Applicant submits that the asserted combination is improper and should be withdrawn.

For these reasons, Applicant respectfully submits that independent claims 1 and 20 are allowable over LEBNER and BEAUDRY or any proper combination thereof, or of the prior art of record. Claims 3-20 and 22-38 are also allowable over LEBNER and

BEAUDRY because of their dependency from an allowable base. Withdrawal of the rejection of claims 1, 3-20 and 22-38 is respectfully requested.

Obviousness-type Double Patenting Rejections are believed Moot

In order to expedite the prosecution of the instant application towards allowance, Applicant has submitted, concurrently herewith, an executed Terminal Disclaimer to render the following rejections moot.

1. Over U.S. Patent No. 6,822,133 in view of U.S. Patent No. 6,329,564

The Examiner asserted that claims 1, 3-20 and 22-38 are unpatentable over claims 1 and 7 of U.S. Patent No. 6,822,133 issued to LEBNER in view of U.S. Patent No. 6,329,564 issued to LEBNER under the judicially created doctrine of obviousness-type double patenting.

2. Over co-pending Application No. 10/625,937 in view of LUTRI

The Examiner asserted that claims 1, 4-20 and 23-38 are unpatentable over claims 1, 3-18 and 20-34 of copending Application No. 10/625937 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

3. Over co-pending Application No. 10/626,783 in view of LUTRI

The Examiner asserted that claims 1, 4-20 and 23-38 are unpatentable over claims 1, 3-19 and 21-36 of copending Application No. 10/626,783 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

4. Over co-pending Application No. 10/625,785 in view of LUTRI

The Examiner asserted that claims 1, 4-13, 17-20, 23-32 and 36-38 are unpatentable over claims 1-12, 16-30 and 32-34 of copending Application No. 10/625,785 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

5. Over co-pending Application No. 10/625,936 in view of LUTRI

The Examiner asserted that claims 1, 4-20 and 23-38 are unpatentable over claims 1-34 of copending Application No. 10/625,936 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

6. Over co-pending Application No. 10/938,163 in view of LUTRI

The Examiner asserted that claims 1 and 20 are unpatentable over claims 1 and 16 of copending Application No. 10/938,163 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

7. Over U.S. Patent No. 6,831,205 in view of LUTRI

The Examiner asserted that claims 1 and 20 are unpatentable over claims 1 and 16 of U.S. Patent No. 6,831,205 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection.

8. Over U.S. Patent No. 6,831,205 in view of LUTRI in further view of U.S. Patent No. 6,329,564 issued to LEBNER, as best can be understood by Applicant.

The Examiner asserted that claims 1 and 20 are unpatentable over claims 1 and 16 of copending Application No. 10/938,163 in view of U.S. Patent Application Publication No. 2004/0106888 issued to LUTRI et al. under the judicially created doctrine of a provisional obviousness-type double patenting rejection. Applicant notes, that the Examiner merely makes reference to LEBNER, however the Examiner above has cited 7 different LEBNER patents and/or patent applications published, of which, Applicant does not know which LEBNER reference the Examiner is referring. Applicant requests the Examiner to correct the above ambiguity in the next Official Office Action.

By the submission of this Terminal Disclaimer, neither Applicant nor Applicant's assignee is making any representation or admission regarding the propriety of the Examiner's judicially created obviousness type double patenting rejection and provisional obviousness-type double patenting rejections or of the propriety of any other double patenting rejection in the absence of the submission of this Terminal Disclaimer. As noted above, the Terminal Disclaimer is being submitted merely in order to expedite the prosecution of the present application towards allowance.

Amendment Proper for Entry

Applicant submits that the instant amendment does not raise any new issues for consideration by the Examiner or any questions of new matter. Further, Applicant submits that, as the instant amendment places the claims into condition for allowance, entry and consideration of this amendment is proper and, therefore, requested.

Application is Allowable

Thus, Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. § 102 and § 103, and under the judicially created doctrine of obviousness-type double patenting and provisional obviousness-type double patenting rejections. Further, Applicant has submitted a Terminal Disclaimer to overcome the obviousness type double patenting rejection and provisional obviousness type double patenting rejections set forth by the Examiner while at the same time not acquiescing in the propriety of such rejection.

Accordingly, Applicant respectfully requests the Examiner to indicate allowance of each and every pending claim of the present invention.

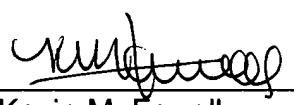
CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention, as recited in each of claims 1, 4-20 and 23-38 which depend from an allowable base claim. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
Michael Lebner



Kevin M. Farrell

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